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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/601,205 | 06/20/2003 | Hermann Duettmann | I/1362 | 7346 |

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EXAMINER

AFREMOVA, VERA

| | |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
|----------|--------------|

1651

DATE MAILED: 05/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|---|--|
| Office Action Summary | Application No. 10/601,205 | Applicant(s) DUETTMANN ET AL. | |
| | Examiner Vera Afremova | Art Unit 1651 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 4/28/2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) 8-11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>12/22/2003</u> . | 6) <input type="checkbox"/> Other: _____ |

RD

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of the Group I (claims 1-7) in the reply filed on 4/28/2005 is acknowledged.

Claims 8-11 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim.

Election was made without traverse in the reply filed on 4/28/2005.

Claims 1-7 are under examination in the instant office action.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7 rejected under 35 U.S.C. 102(b) as being anticipated by US 4,975,279 (Schumacher et al.).

Claims are directed to a drug combination comprising magnesium salt(s) and fibrinolytic(s). Some claims are further drawn to the use of magnesium salts including magnesium sulfate, to the use of fibrinolytic including t-PA (alteplase), streptokinase, and urokinase. Some claims are further drawn to the drug combination components being present in a single formulation or being present in separate formulations.

US 4,975,279 (Schumacher et al.) discloses a drug combination intended for improving myocardial function comprising magnesium salt or magnesium sulfate in cardioplegic solution

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that is combined with fibrinolytic such as t-PA (col. 9, lines 26-34). (s). This drug combination is present in a single formulation after combining and in separate formulations before combining. US 4,975,279 (Schumacher et al.) also discloses another drug combination comprising magnesium stearate and tPA (col. 8, lines 50-66). US 4,975,279 (Schumacher et al.) teaches incorporation of various fibrinolytic including t-PA or alteplase, streptokinase, urokinase (col.5, lines 30-34; col.6, lines 53-69).

Thus, the cited US 4,975,279 (Schumacher et al.) anticipates the claimed invention.

Claims 1, 2, 5, 6, and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,876,757 (McCarty).

Claims are directed to a drug combination comprising magnesium salt(s) and fibrinolytic(s). Some claims are further drawn to the use of fibrinolytic including t-PA, streptokinase, and urokinase. Some claims are further drawn to the drug combination components being present in a single formulation or being present in separate formulations.

US 5,876,757 (McCarty) recognizes magnesium salts as important component for maintenance of vascular integrity and for treating myocardial infarction (whole document including col.1 lines 16-30) and the efficacy of thrombolytic therapy with fibrinolytics including tPA, streptokinase and urokinase for treating myocardial infarction (col. 1, lines 43-50). US 5,876,757 (McCarty) discloses a drug combination comprising magnesium salt and fibrinolytic such tPA in a single and separate formulation(s) (col. 6, lines 18-24).

Thus, the cited US 5,876,757 (McCarty) anticipates the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,975,279 (Schumacher et al.) and US 5,876,757 (McCarty) and US 6,455,560 (Wityak et al.).

Claims are directed to a drug combination comprising magnesium salt(s) and fibrinolytic(s). Some claims are further drawn to the use of magnesium salts including magnesium sulfate, to the use of fibrinolytic including t-PA (alteplase), streptokinase, urokinase, reteplase, anistreplase, etc. Some claims are further drawn to the drug combination components being present in a single formulation or being present in separate formulations.

US 4,975,279 (Schumacher et al.) and US 5,876,757 (McCarty) are relied upon as explained above for the disclosure a drug combination comprising magnesium salt(s) and fibrinolytic(s) in a single and separate formulation(s). The cited reference recognize both components as effective agent for improving myocardial function and treating myocardial infarction. They teach the use of various magnesium salts including magnesium sulfate, stearate, citrate and various fibrinolytic including t-PA (alteplase), streptokinase, urokinase.

In addition US 6,455,560 (Wityak et al.) is relied upon to demonstrate that additional fibrinolytics such as, for example: reteplase, anistreplase (col. 64, lines 59-61), have been known and suggested for drug combination(s) including magnesium salts (col. 63, line 58; col. 64, line 25, line 37).

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Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to combine magnesium salt(s) and finbinolytic(s) as a drug combination with a reasonable expectation of success for improving myocardial function and treating myocardial infarction because magnesium salt(s) and finbinolytic(s) have been taught and/or suggested separately and together for improving myocardial function and treating myocardial infarction. Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.

The claimed subject matter fails to patentably distinguish over the state art as represented by the cited references. Therefore, the claims are properly rejected under 35 USC § 103.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (571) 272-0914. The examiner can normally be reached from Monday to Friday from 9.30 am to 6.00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached at (571) 272-0926. The fax phone number for the TC 1600 where this application or proceeding is assigned is (571) 273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology center 1600, telephone number is (571) 272-1600.

Vera Afremova, AU 1651

May 12, 2005



VERA AFREMOVA

PRIMARY EXAMINER